K073714

510(k) Summary

MAR 19 2008

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter's Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726
1. (b)	***Manufacturer Address:***	Orthocrat, Ltd. 35 Efal St, 12th floor Petach-Tikva Israel, 49511
	Mfg. Phone:	972-3- 929-0929
	Contact Person:	Zeev Glozman, CEO
	Date:	December 27, 2007
2.	***Device & Classification Name:***	Imaging Processing System (Class 2), Product Code LLZ, 21 CFR 892.2050 – Tradename of device: TraumaCad Release 2.0
3.	***Predicate Device:***	TraumaCad Release 1.0 (K042816) & Agfa Orthopedic Software for Impax (K071972)
4.	***Description:***	TraumaCad allows surgeons to evaluate and manipulate digital images while performing various pre-operative surgical planning and evaluation of images. This software application enables surgeons to plan operations on screen, execute complex measurements in a click, and facilitate the film-less orthopedic practice. The program features full PACS integration and an extensive regularly updated library of digital templates from leading manufacturers. TraumaCad supports DICOM and enables the importing and exporting any PACS file (X-ray, CT or MR) from a central PACS system, a CD or from a local workstation. JPG, scanner or digital camera images can also be imported. TraumaCad software is installed and runs locally on a computer (PC) and interacts with a PACS system. Both a standalone and a client/server version of TraumaCad are available.
5.	***Intended Use:***	The TraumaCAD program is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.
6.	***Comparison of Technological Characteristics:***	With respect to technology, TraumaCad Release 2.0 is substantially equivalent to its predicate devices. Besides including 3D templating capability, the main purpose of this 510(k) was to obtain marketing clearance for additional features for aiding foot, knee, hip, spine, and pediatric surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 19 2008

Orthocrat, Ltd.
% Mr. George J. Hattub
Senior Staff Consultant
MedicSense, USA
291 Hillside Avenue
SOMERSET MA 02726

Re: K073714
Trade/Device Name: TraumaCad Release 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 27, 2007
Received: December 31, 2007

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073714

Device Name: TraumaCad Version 2.0

Indications For Use: The TraumaCAD program is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073714